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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,736	02/22/2002	Marco Mastrodonato	11109-004	8421

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PENNIE AND EDMONDS  
1155 AVENUE OF THE AMERICAS  
NEW YORK, NY 100362711

EXAMINER

HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

4

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

10/080,736

Applicant(s)

MASTRODONATO ET AL.

Examin r

Michael C. Henry

Art Unit

1623

-- The MAILING DATE of this c mmunication appears on the cover sheet with the c rrespondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_ .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-29 and 60-65 is/are allowed.
- 6) ☒ Claim(s) 1-11 and 30-59 is/are rejected.
- 7) ☒ Claim(s) 4-7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_ .
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_ .

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### **DETAILED ACTION**

Claims 1-65 are pending in application

#### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### ***Claim Objections***

Claims 4-7 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 1, recites that "the viscosity of the composition is from about 50 to about 500 centipoise. However, claim 4 which is dependent on claim 1, recites that "the viscosity of the composition is from about 90 to about 1000 centipoise, which is a broader range of viscosity than claim 1. Thus, claim 4 is of improper dependent for failing to further limit the subject matter of claim 1. Claim 5 is objected to because it depends on claim 4. Claim 6 is objected to because aforementioned reasons. Claim 7 is objected to because it is dependent on claim 6.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 recites the phrase, "having a molecular weight from about 1.6 and 2.2 million daltons " in lines 3 and 4. However, this phrase renders the claim confusing, vague and indefinite. More specifically, it is unclear which of the two molecular weight values is being claimed, and what is the upper limit values of the molecular weight. It appears that the correct phrase should be, "having a molecular molecular weight from about 1.6 to about 2.2 million Daltons."

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The specification, while being enabling for the treatment of the inflammation or mucositis, does not reasonably provide enablement for the prevention of the inflammation or mucositis. First, the composition does not prevent inflammation or mucositis. In addition, the composition treats the already existing inflammation or mucositis in the individuals. The prevention of inflammation or mucositis is not enabled since the said conditions do not have a single recognized cause. For example, mucositis can result from chemotherapy and radiation treatments which involves a variety of chemotherapeutic agents and ionizing radiation which causes inflammatory changes. In addition, an individual susceptibility to mucositis depends on age, preexisting conditions like periodontal disease,

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hematologic or head and neck malignancies, and acquired immunodeficiency syndrome. These are only a few of the factors that contribute to the said condition in people. Therefore, the prevention of the said disease by one method is not enabled by the instant disclosure. It should be noted that this rejection encompasses claims 30,39,47,48,54,55 and all the dependent claims thereof (i.e., claims 31-38, 40-46,49-53, 56-58).

***Allowable Subject Matter***

The following is an examiner's statement of reasons for allowance: The examiner has found claims 1-11 and 30-59 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record provided, the 112 rejections and the objections are overcome. Claims 12-29 and 60-65 are found to be unobvious over the prior art of record and therefore to be allowable over the prior art of record. The present invention relates to a composition, comprising hyaluronic acid (of special molecular weights), or a pharmaceutically acceptable salt thereof, polyvinylpyrrolidone (of special intrinsic viscosities) and water, and method of using the composition. The very relevant prior art document (US 4,965,253) to this invention discloses a composition, comprising hyaluronic acid, polyvinylpyrrolidone and water.

However, though the composition of the present invention are similar in terms of the type of components to those claimed in the prior art document, they possess differences which includes, physical properties, like intrinsic viscosities, molecular weights and percent ratios of constituents that are unobvious to those of the prior art. These differences impart special properties, features or effects to the composition and subsequently different utility, that are unobvious to those of the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

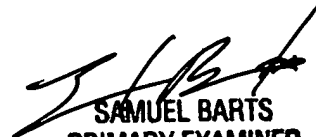
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 703 308-7307. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703 308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

May 14, 2003.

  
SAMUEL BARTS  
PRIMARY EXAMINER  
GROUP 1200